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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,303	11/27/2001	Robert C. Beck	2446	1374

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Beck & Tysver, P.L.L.C.
2900 Thomas Avenue S., Suite 100
Minneapolis, MN 55416

EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,303

Applicant(s)

BECK, ROBERT C.

Examiner

Matthew F DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9, 18-24 and 27-30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 7-9, 18-24 and 27-30 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. With regards to the claim objection, the examiner is viewing the claims 29, 30 and 31 in view of this last response.

Claim Rejections - 35 USC § 112

2. The 112 Rejection made in the prior office action is withdrawn because of arguments and amendments.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 7-9, 18-24, 27- 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Nash et al. (USPN 6,524,323).

Nash et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said

therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figures 10, 11, 16, 17; Column 26, line 52 – Column 29, line 40 and entire reference)

As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath.

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and the injection fluid drops to a second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen.

As to claim 27, wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection.

3. Claims 7-9, and 18-24, 27- 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Levin et al. (USPN 6,592,567).

Levin et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said

therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figures 3, 7 and entire reference)

As to claim 18, wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath. (Figures 3, 7 and entire reference)

As to claim 9, wherein said fluid is injection at a first injection pressure above the blood pressure in the vessel and the injection fluid drops to second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen. (Figures 3, 7 and entire reference)

As to claim 27, wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection. (Figures 3, 7 and entire reference)

4. Claims 7-9, 18-24, and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (USPN 5100425).

Fischell et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located

distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen.

Fischell et al. also discloses an infusion means and a discharge means.
(Column 5, line 62- Column 6, line 15)

5. Claims 7-9, 18-24, and 27-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Zadno-Azizi et al. (USPN 6,605,074).

Zadno-Azizi et al. discloses inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, inserting and advancing an interventional device to a treatment location, said interventional device of type having; a therapy balloon for delivering treatment, and a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon; injecting fluid out of said gap to promote retrograde flow into said discharge lumen. (Figure 24A, and entire reference)

Zadno-Azizi et al. also discloses an infusion means and a discharge means.
(Figure 24A, and entire reference)

Response to Arguments

6. Applicant's arguments and amendments filed 8/16/04 have been fully considered and are not persuasive.

7. The applicant argues the "wall attachment" achieves a "Coanda effect" and this is the distinguishing feature from the prior art.

8. The examiner has read through the claims and does not see where the limitations of a wall attachment are in the independent or dependent claims. The only language that is similar to the described language in the remarks section is that the fluid will be projected in an initial direction adjacent a wall of said elongated body, which is true in all catheters. The fluid would have to be projected in a direction adjacent a wall because the fluid would have to exit the catheter in a direction adjacent a wall. The applicant seems to be arguing that the fluid is projected through a wall attachment thus achieving the Coanda effect.

9. Since the limitation the applicant is arguing is not in the claim and therefore the limitation is given no patentable weight.

10. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within


TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (703) 308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Matthew DeSanto
Art Unit 3763
October 14, 2004


NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700